Calendar No. 128

103D CONGRESS, 1st Session | SENATE | REPORT 103–82

BIOTECHNOLOGY PATENT PROTECTION ACT OF 1993

JULY 1 (legislative day, JUNE 30), 1993.—Ordered to be printed

Mr. BIDEN, from the Committee on the Judiciary, submitted the following

REPORT

[To accompany S. 298]

The Committee on the Judiciary, to which was referred the bill (S. 298) relating to an amendment to title 35, United States Code, to provide conditions for the patentability of biotechnological process patents, and for other purposes, having considered the same reports favorably thereon and recommends that the bill do pass.

CONTENTS

I. PURPOSE

The purpose of S. 298 is to amend the Patent Code to provide additional protection for biotechnological inventions. Senate bill 298 will eliminate barriers to biotech process patenting, and thereby increase innovation and stimulate the development of new products and processes.

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II. Legislative History

Senate bill 298, the Biotechnology Patent Protection Act of 1993, was introduced by Senator DeConcini and Senators Hatch, Heflin, Kennedy, Kohl, Lautenberg, Specter, Grassley, Brown, and Domenici on February 3, 1993. It was polled out of the Judiciary Subcommittee on Patents, Copyrights and Trademarks on March 16, 1993. Senate bill 298 was ordered reported by the full Judiciary Committee on May 16, 1993, by unanimous consent.

The Biotechnology Patent Protection Act has its origins in the 101st Congress, when Senator DeConcini and Representative Boucher each introduced the Biotechnology Patent Protection Act of 1990. The respective bills differed only in their effective date.

After introducing these bills, Representative Boucher and Senator DeConcini as well as Representative Kastenmeier, then Chairman of the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, solicited the views of the Department of Commerce. In a July 1990 response letter, the Department expressed agreement with the need for the legislation but voiced objections to the provisions amending section 337 of the 1930 Tariff Act, as well as to title 35 of the United States Code, which would extend enforcement of the rights of a patent claiming biotechnological material used in the manufacture of a recombinant product.

In consideration of the views of the Department of Commerce, Representative Boucher introduced a second bill, H.R. 5664, in the 101st Congress. A hearing in the House was held, but there was no further action on these bills in the 101st Congress.

In the 102d Congress, Senator DeConcini introduced S. 654, the Biotechnology Patent Protection Act of 1991, on March 13, 1991, with Senators Hatch, Kohl, Lautenberg, Specter, and Grassley. Representative Boucher introduced companion legislation, H.R. 1417, in the House of Representatives on the same day. As introduced in the 102d Congress, S. 654 and H.R. 1417 had identical language to H.R. 5664 from the 101st Congress.

After the introduction of S. 654, Senator DeConcini wrote to the Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, Harry F. Manbeck, Jr., to express concern that the bill's positive effects would be unnecessarily circumscribed by overruling *In re Durden*[1] in cases where only a single patent issues. Wendell L. Willkie II, the General Counsel of the Department of Commerce, responded to the DeConcini letter on June 10, 1991, stating the Commerce Department's support for S. 654 and suggesting an amendment to alleviate Senator DeConcini's concerns.

On June 12, 1991, the Subcommittee on Patents, Copyrights and Trademarks held a public hearing on S. 654. On July 25, 1991, the Subcommittee reported S. 654 to the full Committee with an amendment in the nature of a substitute that incorporated the suggested language in the Willkie letter. Senate bill 654 as amended favorably passed the Judiciary Committee unanimously on November 21, 1991. The Senate took up S. 654, with an amendment in the nature of a substitute, and passed the bill unanimously on September 18, 1992. The amendment, offered by Senator Heflin, cre-

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[1] 763 F.2d 1406 (Fed. Cir. 1985).

ated remedies for patented "host cells" and other essential intermediates and is now title II of S. 298.

Title I of S. 298 is identical to S. 654 except that it applies exclusively, rather than primarily, to biotechnological processes.

III. Discussion

A. Background

"Biotechnology" is a broad term coined to encompass manmade process which manipulate biological components. The Office of Technology Assessment defines biotechnology as "any technique that uses living organisms (or substances from those organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses."[2]

Biotechnology is a multidisciplinary science, combining biology, chemistry, material science, physics, computer science, and medicine. It is used in diverse industries from pharmaceuticals, agriculture, and veterinary medicine to environmental cleanup and new energy resources. Widely known products made with the use of biotechnology include home pregnancy tests, diagnostic tests for human immunodeficiency virus (HIV), insulin, sweeteners such as aspartame (the sweetener marketed as Nutrasweet), and the enzyme used to turn glucose into highly sweet fructose.

Man has used processes involving biological organisms for hundreds of centuries, and continues to use them in a vast array of areas today. Yeast, a fungus used for fermentation to produce alcoholic beverages and to leaven dough, is one example of an organism that has been processed since the dawn of history. The best beef and pork in the world are the result of selective crossbreeding, and more recently, of artificial insemination. Penicillin and other naturally occurring antibiotics are commercially produced with microorganisms, and the 1992 Winter Olympic Games produced snow by using organisms that promote ice crystallization.

Today's biotechnology is far more complex than that of yesteryear. In the 1950's, Watson and Crick discovered the deoxyribonucleic acid (DNA) double helix, a complex molecule made of billions of single atoms which functions as a genetic template. The basis of much of the biotechnology industry today is the elucidation of relatively minute sections of DNA. Until the advent of the computer chip and advanced electronics, efforts to determine the makeup and function of these minute sections were essentially trial and error. Biotechnology has made it possible to create and test molecules with relative precision. The capability of creating these organic molecules has led to dramatic breakthroughs in the ability to improve human life.

All living things are composed of cells, from one-celled bacteria to giant multicellular whales. Each cell contains a complete genetic "blueprint" of the organism encoded in a long molecule, DNA. DNA guides the construction and functions of the organism by directing cellular synthesis of proteins.

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[2] U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: Ownership of Human Tissues and Cells-Special Report," OTA–BA–337 (Washington, DC: U.S. Government Printing Office, March 1987).

Sections of DNA, called genes, contain chemical instructions that guide the cell's machinery in constructing proteins. Proteins give living things their unique characteristics. Some proteins give structure to living organisms. Others mediate the chemical reactions that are necessary for organisms to function. Proteins are sequences of amino acids whose major role is to act as catalysts for chemical reactions in the body. When acting as a biocatalyst, proteins are known as enzymes.

Some people are born with problems with their DNA in certain genes. These genetic defects scramble the coded instructions in the gene, causing the cell to produce a defective protein or no protein at all. This has serious consequences for the health of the individual. If the function of the defective or missing protein is important, the person may die without it. In other cases, normally functioning genes may develop problems due to infection, age or other factors. These genes may develop abnormal characteristics, leading in some cases to cancer or arthritis.

Because proteins can regulate chemical reactions, determining which specific protein performs which function is vitally important in fighting disease. For example, by preventing a given chemical reaction from occurring by removing or tying up the reaction-specific catalyst, it may be possible to stop the growth of diseased cells. Similarly, by enabling the occurrence of a given reaction by supplying a missing gene, an organism's own system can be forced to produce beneficial chemicals, such as insulin. Biotechnology is responsible for these marvels of science.

Several technologies are available for performing these feats, including recombinant DNA. Recombinant DNA technology uses naturally occurring enzymes to clip out fragments of DNA and then insert the fragment containing a specific gene into a different cell, altering that cell so that it carries a new genetic message. This technology has enabled scientists to successfully generate human insulin with *E. coli,* bacteria inhabiting the human digestive tract.

These microorganisms then grow at a tremendous rate; some have a generation time of 30 minutes or less. The multiple copies of the microbe produce large amounts of the desired protein. Consequently, proteins that occur in minute quantities in nature can be produced in large quantities through recombinant technology. The proteins produced by the microorganisms are also free of viral contamination that might contaminate the protein if extracted from human tissue or fluids.

This complex research is expensive and can take many years to yield practical results. It is estimated that it takes an average of 12 years to bring a drug from discovery through final FDA approval.[3] The biotechnological industry contends that the average cost of discovery and bringing a single drug to market today exceeds $230 million.[4] In combination, private- and government-sponsored research exceeded $4 billion in 1988, and the industry still

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[3] Thompson, "High Cost of Rare Diseases, When Patients Can't Afford to Buy Lifesaving Drugs," Washington Post Health, June 25, 1991.

[4] "Anticompetitive Abuses of the Orphan Drug Act; Invitation to High Prices," hearing before the Senate Judiciary Subcommittee on Antitrust, Monopolies and Business Rights, 102d Cong., 2d sess. (1992), (statement of John P. McLaughlin, vice president and general counsel of Genentech, Inc.), (citations omitted).

continues to grow because of the enormous need for biotechnology products.[5]

Commerical successes in 1990 garnered the U.S. biotechnological industry sales of $2.9 billion, doubling the sales of 1989 and quadrupling the amount for 1988.[6] However, the biotechnology industry faces formidable challenges in continuing this groundbreaking research. Japan has targeted pharmaceutical development as an industry of vital economic importance.[7] Europe invests heavily in biotech research and actually leads in the production of monoclonal antibodies.[8] Therefore, it is vitally important that the United States maintain its edge in this competitive and fast paced industry by continuing its investment in biotechnical breakthroughs.

B. Biotechnology patenting

Biotechnology, an intensely competitive industry, requires effective, enforceable intellectual property laws to deter piracy of its inventions. Currently, however, patent protection for biotech products is difficult to obtain under current U.S. law and is unavailable in many foreign countries. Without such protection, venture capitalists fearful of an inability to recover their investment may refuse to provide R&D costs which, in turn, jeopardizes future biotechnological advancements.[9]

Biotech products are often the recombinant versions of a naturally occurring substance usually found in an animal or plant. When the scientific literature or other available information reveals that the naturally occurring version of the protein has been purified to some extent, even if it has not been definitively characterized, a patent for the recombinant version may be denied for lack of novelty. In patent law terms, the product has already been discovered.[10] This may occur even when the amount of the natural product that has been isolated is insufficient for any practical use and the method employed cannot provide practical quantities of the material. Inventors of some recombinant versions of naturally occurring products have found it difficult to obtain adequate patent protection because of the mere existence of literature disclosing incomplete information about the natural protein.[11]

A second hurdle inventors must overcome is that a patent application for a recombinant product may be denied because it is deemed obvious, and thus unpatentable, despite its novelty. In many cases, although the protein has never before been isolated in

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[5] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: U.S. Investment in Biotechnology—Special Report," OTA–BA–401. (Washington, DC: U.S. Government Printing Office, July 1988.)

[6] "Biotechnology Patent Protection Act of 1991," hearing on S. 654 before the Judiciary Subcommittee on Patents, Copyrights and Trademarks, 102d Cong., 1st sess. (1991), [hereinafter hearings], (statement of Henri Termeer, president and CEO of Genzyme Corporation, on behalf of Industrial Biotechnology Association).

[7] The President's Council on Competitiveness, "Report on National Biotechnology Policy," at 5, Washington, DC (February 1991).

[8] Id.

[9] U.S. Congress, Office of Technology Assessment, "New Developments in Biotechnology: Patenting Life—Special Report," OTA–BA–370 at 101 (Washington, DC: U.S. Government Printing Office, April 1989), [hereinafter OTA report].

[10] See generally, Murashige, "Section 102/103 Issues in Biotechnology Patent Prosecution," 16 A.I.P.L.A., Q.J. 294, 303–04 (1988–89); Andrews, "Unaddressed Question in the Amgen Case," N.Y. Times, Mar. 9, 1991, at A30.

[11] A natural protein is a protein encoded by DNA that occurs in nature. A recombinant protein is a protein encoded by DNA that has been produced by combining genetic material from at least two different sources.

a substantially pure form or the product is not well characterized prior to the recombinant synthesis, if its basic properties and some aspects of its structure are known, the Patent and Trademark Office (PTO) may assert that the use of recombinant technology to make a pure form of such a product is obvious. The ability to obtain a patent for a purified version of a protein merely to block the use of a process to make commercially viable quantities of a recombinant version of the protein has been criticized.[12]

The mere existence of a previously discovered protein should not, by itself, always preclude the issuance of a patent for a recombinantly created version of the same protein. The rationale under which a patent may be granted for a product existing in nature is that in its natural form, such a product is not available and useful to the public without further isolation and purification. The law as currently expressed provides that to be considered obvious:

> the differences between the subject matter sought to be patented *and the prior art* [must be] such that the *subject matter as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[13]

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) and its predecessor, the U.S. Court of Customs and Patent Appeals (C.C.P.A.), have reiterated many times that an applicant's disclosure in a patent application cannot be treated as prior art in determining the obviousness of the claimed invention.[14] The court has also emphasized that the invention as a whole must be considered in assessing obviousness.[15] Finally, the court has cautioned that a patentability determination must be made as of the time the invention was made, and not as part of a hindsight reconstruction of the invention given the applicant's disclosure.[16]

Because questions of novelty and obviousness often preclude product patents, the biotechnology industry has become heavily dependent upon process patents. Yet, product patents are generally considered to provide better protection for drugs than process or use patents because the latter two types usually can be circumvented more easily. Additionally, it may be more difficult to detect the infringement of a process patent than the product patent because products are available to the public, but the processes used to make them are kept secret within the walls of a manufacturer.

The biggest problem facing the U.S. biotech industry is the lack of clarity in the rules for patentability of biotech processes. Sound investment decisions require a degree of economic certainty. The lack of legal certainty for biotechnology process patents affects the

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[12] See Merges & Nelson, "On the Complex Economics of Patent Scope," 90 Colum. L. Rev. 839, 903–04 (1990). See also *Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 666 F.Supp. 1379 (N.D. Cal. 1987), modified on reconsideration, 678 F.Supp. 1429 (N.D. Cal. 1988), summ. judgment granted, 707 F.Supp. 1547 (N.D. Cal. 1989), aff'd in part, rev'd in part, vacated in part, 927 F.2d 1565 (Fed. Cir. 1991), (reserving for further analysis by the district court the issue whether a patent on a purified protein should serve to block a patent on a recombinant version of the same protein).

[13] 35 U.S.C. 103 (1988), (emphasis added).

[14] See, e.g., *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1567–88 (Fed. Cir. 1987), cert. denied, 481 U.S. 1052 (1987); *In re Katz*, 687 F.2d 450 (C.C.P.A. 1982).

[15] See *John Deere Co.* v. *Graham*, 333 F.2d 529 (8th Cir. 1964), aff'd 383 U.S. 1 (1966).

[16] *In re Kuehl*, 475 F.2d 658, 663–65 (C.C.P.A. 1973).

probability of return on investment and inhibits some venture capital investments.[17]

C. In re Durden

A major defect in U.S. patent case law has led the PTO to an inconsistent application of *In re Durden,*[18] a nonbiotech patent case, to important biotechnology-derived processes. A PTO supervisor noted that the use of this case as a basis for rejecting process patent claims in biotechnology is on the rise, as many examiners routinely apply it to biotechnology issues.[19]

Durden involved a challenge to the denial of a patent for a process to make a novel chemical. The process was similar to that of a previously issued patent; however, the *Durden* process utilized a novel and nonobvious, but related, starting material and produced a novel and nonobvious, but related, end product. It appeared predictable that once the new starting material and new product were disclosed, the old process would work with the new starting material to produce the new product. The court in *Durden* concluded, in the narrow factual context of that case, that the chemical process was obvious and not patentable, even though both the specific starting material employed and the product obtained were novel and nonobvious.

The Federal Circuit thus held, on the facts before it, that a process using a patentable "starting compound" to make a patentable "final compound" was not patentable. The Federal Circuit indicated in its opinion, however, that the patentability of each process must be evaluated on case-by-case basis. In following *Durden,* the PTO believes that it cannot interpret section 103 to require that a process be held patentable merely because a patentable material was either used or made by that process.

Consequently, the PTO has cited *Durden* in denying patents to processes for producing proteins which use as starting materials, DNA, vectors or biological microorganisms made by recombinant DNA technology. This denial of process claim protection is routine even if the starting materials are found by the PTO examiner to be novel and nonobvious and, therefore, patentable in their own right.

Durden precludes needed patent protection for biotechnology processes and has been roundly criticized by commentators and legal practitioners.[20] Since the *Durden* decision it has become increasingly difficult to obtain process patent protection in the United States for genetic engineering inventions. Although some inventors overcome *Durden* rejections, the uncertainty in this area of the law has lead to inconsistent results by examiners.

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[17] OTA report, supra note 10.

[18] 763 F.2d 1406 (Fed. Cir. 1985).

[19] Wiseman, "Biotechnology Patent Practice—A Primer," 16 A.I.P.L.A., Q.J. 394, 411 (1988–89). See generally Litman, "Obvious Process Rejection Under 35 U.S.C. 103," 71 J. Pat. and Trademark Off. Soc'y 775 (1989); Wegner, "Much Ado About Durden," 71 J. Pat. and Trademark Off. Soc'y 785 (1989).

[20] See Murashige, supra note 11; Wegner, supra note 20; Comment, "The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?" 24 J. Marshall L. Rev. 263 (1990); McAndrews, "Removing the Burden of Durden Through Legislation: H.R. 3957 and H.R. 5664," 72 J. Pat. and Trademark Off. Soc'y 1188, (1990); Beier and Benson, "Biotechnology Patent Protection Act," 68 Denv. U.L. Rev. 173 (1991).

The inconsistent application of *Durden* by the PTO has also led to severe delay or denial of issuance of process patent protection to deserving inventors. The Federal Circuit acknowledges that there have been conflicting views on this issue both in the PTO Board of Appeals and in the C.C.P.A.[21]

Moreover, case law exists in this area which conflicts with the *Durden* reasoning and which would be more appropriately applicable to biotechnology process patents.[22] The application of *Durden* by the PTO to biotechnology cases, which involve microorganisms, conflicts with *In re Mancy*.[23]

In *Mancy,* the court held that a standard method of culturing microorganisms to produce antibiotics could not be treated as prior art in determining the patentability of a similar method using a patentable microbe to produce an antibiotic therefrom. In other words, novelty and nonobviousness of the microbe imparted patentability to a method using it.

To the detriment of biotechnology process patent applicants, the PTO has felt constrained to follow *Durden* rather than *Mancy.* More troubling is the fact that the reasoning in *Mancy* is the law for inventions in Europe and Japan, where the patenting of process inventions that use patentable starting materials has long been recognized.[24]

The Federal Circuit revisited the issue of the patentability of processes in *In re Pleuddemann.*[25] In that case the patentee had a patent to a starting material that he used in a process to make a patentable final product. Apart from the use of the patented starting material, the method (process) of making the final product was admittedly already known. The Federal Circuit held that the method of using the patented starting material to produce the patentable final product was patentable in this particular case.

Although the Federal Circuit attempts to distinguish *Pleuddemann* from *Durden,* it is difficult, if not impossible, to reconcile these two cases. It is not clear why a method of using a starting material should be treated differently, for purposes of determining nonobviousness, from a method of making the end product. Yet, under *Pleuddemann,* the former is per se nonobvious, while the latter is not.

The PTO and the courts continue to apply *Durden* to reject claims involving methods of using novel DNA sequences and other recombinant intermediates to make protein products. The classic *Durden* rejection maintains that a process of making a protein using a novel DNA sequence is obvious, because others have previously used the same process with other DNA sequences to make other proteins. As a result of *Pleuddemann,* it might be asserted that recombinant DNA patent applications no longer need fear such a *Durden* rejection of process-of-using claims which are based upon a novel DNA sequence encoding a desired protein X. Unfortunately, biotechnology companies have reported that the PTO has generally rejected this reasoning.

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[21] *Durden,* 763 F.2d at 1409.

[22] See, e.g., *In re Mancy,* 499 F.2d 1289 (C.C.P.A. 1974). See also *In re Kuehl,* 475 F.2d 658 (C.C.P.A. 1973).

[23] 499 F.2d 1289 (C.C.P.A. 1973).

[24] *Termeer,* supra note 7.

[25] 910 F.2d 823 (Fed. Cir. 1990).

A prudent attorney certainly would seek to use *Pleuddemann* to the client's advantage by rephrasing "a recombinant DNA process of making protein X" into a *Pleuddemann*-style process-of-using claim, such as, "contacting DNA with cellular enzymes or with a transcription/translation apparatus." However, as noted above, examiners are asserting that such claims are really a process-of-making claim in disguise.

Alternatively, some have argued that given the right case on appeal, the Federal Circuit might, at some future date, reverse *Durden* by applying a *Pleuddemann*-type analysis, finding that making is also not obvious because the *Durden*-type rejection presumes the new starting material or novel product to be prior art. While this possibility is consistent with the analysis in *Pleuddemann,* there clearly is no certainty that such a future decision will ever occur, particularly as the court has rejected this approach over the past 20 years.[26]

Some had hoped the November 9, 1990, rehearing of *In re Dillon*[27] would provide guidance regarding *Durden* and perhaps overrule it. In very clear dicta, the Federal Circuit summarized its attitude regarding *Durden* as follows:

> Suffice it to say that we do not regard *Durden* as authority to reject as obvious every method claim reading on an old *type of process,* such as mixing, reacting, reducing, etc. The materials used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials are used or result from the process are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of *Durden*.[28]

Therefore, *Durden* is very much alive, but weakened and unpredictable in its application by the individual patent examiner, the Board of Appeals and Interferences, and the courts.

Durden-type rejections remain an even greater problem following *Pleuddemann* because the Federal Circuit explicitly avoided questioning *Durden* as good law, and distinguished *making* and *using* as two different types of process claims.[29] A patent applicant may ask what new route to protect a recombinant DNA process claim is available after *Pleuddemann*. The answer is not clear because *Pleuddemann* does not address that question. One could rephrase *making* claims as *using* claims, but PTO has rejected this approach and it could take years before it is known whether the Federal Circuit agrees. The committee believes that congressional passage of

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[26] Once again, there is an appeal now before the Federal Circuit, which raises the conflict between *Durden, Albertson,* and now *Pleuddemann.* See *In re Ochiai* (Appeal No. 92–1446). Although *Ochiai* has been orally argued, a final decision by the Federal Circuit is not imminent. Similar to *Pleuddemann,* the *Ochiai* appeal creates further confusion by appearing to be a future solution to a problem the Federal Circuit refuses to resolve.

[27] 919 F.2d 688 (Fed. Cir. 1990), (en banc).

[28] *Id.* at 695 (emphasis in original).

[29] *Pleuddemann,* 910 F.2d at 827.

clear statutory language that explicitly removes the *Durden*-style rejection is a more direct and unambiguous route to protect recombinant DNA method-of-making protein claims.

The PTO, along with the Industrial Biotechnology Association and other witnesses, has opined that *Pleuddemann* has not clarified the law and leaves patent applicants unable to predict with reasonable certainty whether they can obtain process patents of this nature. Testifying before the House Judiciary Subcommittee on Courts, Intellectual Property and the Administration of Justice, then Patent Commissioner Manbeck stated that, "the distinction between *Pleuddemann,* on the one hand, and *Durden* and *Albertson*[30] on the other hand is esoteric, at best."[31] Appearing with Manbeck, the Solicitor of the PTO, Fred McKelvey, responded affirmatively to Representative Boucher's inquiry that the "*Pleuddemann* decision doesn't do anything to clear up the confusion that exists in the law currently."[32]

Manbeck further testified that the PTO will continue to have difficulty during the examination of patent applications relating to processes in resolving the seemingly unnecessary issue of whether a process is one for "making" or "using" a patentable product.

Title I of S. 298 amends section 103 of title 35, the Patent Code, to effectively avoid the Federal Circuit decision in *In re Durden.* Title I resolves the *Durden* dilemma by providing that a biotechnological process of making or using a product may be considered nonobvious if the starting material or resulting product is novel and nonobvious. Additionally, title I provides certainty and needed incentives for the biotechnology industry, incentives to grow and not be deterred by our patent laws. It will allow the United States to continue to lead biotechnology research worldwide and will provide essential protection to an industry that generates billions of dollars for the U.S. economy.

D. Importation

Title II of S. 298 provides a solution to another deficiency in our law that has created an obstacle for the U.S. biotechnology industry. Under present U.S. patent law, the holder of a patent to an organism, such as a host cell or part thereof, such as a DNA sequence or vector, can preclude another from using the organism in the United States. However, without patent protection for the process of using that organism, the inventor has no effective remedy against someone who takes the patented organism to another country, uses it to produce a protein-based product, and imports that product back into the United States.

The lack of an effective remedy to prohibit this blatant exploitation of patented U.S. technology is illustrated by Amgen, Inc.'s inability to prevent importation of erythropoietin (EPO) into the United States from Japan by Chugai Pharmaceutical Co. This controversial and public patent dispute in biotechnology[33] involved the

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[30] 332 F.2d 379 (C.C.P.A. 1964).

[31] "Biotechnology Patent Protection: Hearing on H.R. 3957 and H.R. 5664," before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Cong., 2d sess. 18 (1990) (statement of Harry F. Manbeck, Jr., Asst. Sec. and Commissioner of Patents and Trademarks, U.S. Dept. of Commerce).

[32] Id. at 27.

[33] *See, e.g.,* Andrews, *Mad Scientists,* BUS. MONTHLY, May 1, 1990, at 54.

innovative product, recombinant erythropoietin (rEPO), as litigated in *Amgen, Inc.* v. *Chugai Pharmaceutical Co.*[34] Amgen's patent, at the time of that litigation, did not contain a claim to a process of making EPO using patented host cells. The International Trade Commission (ITC) refused to interpret the claims to the host cells alone as constituting a process claim under existing law. Consequently, Amgen was denied relief based upon its patented host cells since the ITC held that such claims to "host cells" *per se* were not process of making claims.

In this case, Amgen had conducted ground-breaking scientific research enabling it to produce commercially viable commodities of rEPO.[35] This major scientific and medical advance did not, however, give Amgen sufficient patent rights to prevent importation of competing products from Japan even though Amgen's competitors could not produce rEPO within the United States without infringing Amgen's patents.

Amgen is not the only entity facing this problem today. There are other small biotechnological companies and universities that have obtained only host cell protection. Indeed, some of these entities many have given up rights to process claims in order to receive protection of the host cell.

Title II specifically addresses the dilemma faced by biotechnology companies and universities trying to protect their patented biotechnological materials by providing a remedy against infringing foreign competitors. After the passage of this legislation, U.S. innovators will no longer be forced to watch helplessly as foreign companies reap the harvest to which the innovator is entitled.

S. 298 will create a level playing field by allowing a patent owner to enforce a patent claiming a host cell against a foreign manufacturer who imports a product into the United States made using the host cell. It makes no sense that U.S. patents of this nature are only enforced against U.S.-based manufacturers.

E. Additional benefits

Although not the primary purpose of the legislation, S. 298 also offers the ancillary benefit of reducing the increasingly high transaction costs associated with patent prosecutions and litigation by providing certainty in the law for both the PTO and the process patent applicants.[36] The high costs of such litigation may seriously drain the research budgets of biotech companies.[37] Unfortunately, the chilling effect of a process rejection has fallen most heavily upon those who lack the resources to pursue process patents, small companies and universities. The most disturbing potential ramification of inadequate intellectual property protection is that some promising therapies will not be pursued.

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[34] 705 F. Supp. 94 (D. Mass. 1989), *aff'd in part and rev'd in part,* 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied,* 112 S.Ct. 169 (1991).

[35] As of early 1993, Amgen is currently alone on the market with its version of EPO, EPOGEN, because of provisions of the Federal Food, Drug, and Cosmetic Act, § 527, 21 U.S.C. 360(cc) (1988). Under this Act, the sponsor of a new drug or biologic can, if certain market criteria are met, obtain market exclusivity for a period of seven years. In this case, Amgen obtained market exclusivity because it established that rEPO was a safe and effective therapy for treatment of chronic renal failure, the relevant patient population of which is less than 200,000.

[36] OTA Report, *supra* n. 10, at 56–58.

[37] U.S. Congress, Office of Technology Assessment, "Commercial Biotechnology: An International Analysis," 403 (1984).

In many respects this legislation is considered a continuation of the congressional policy behind the Process Patent Amendments Act of 1988. Without appropriate process claims in their patents, biotechnology inventors cannot take advantage of the benefits of the act. As a consequence, the advantages of the act are essentially nullified for the biotechnology industry. Finally, S. 298 helps harmonize our laws with those of our trading partners, at least with regard to biotechnology intellectual property.

IV. Vote of the Committee

On March 16, 1993, the Subcommittee on Patents, Copyrights and Trademarks reported S. 298 to the Committee on the Judiciary. On May 6, 1993, the Committee on the Judiciary, a quorum being present, favorably reported by unanimous consent S. 298.

V. Text of S. 298 As Reported

[103d Cong., 1st sess.]

A BILL To amend title 35, United States Code, with respect to patents on biotechnological processes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—BIOTECHNOLOGICAL PROCESS PATENTS

SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS SUBJECT MATTER.

Section 103 of title 35, United States Code, is amended—

(1) in the first unnumbered paragraph by inserting "(a)" before "A patent";

(2) in the second unnumbered paragraph by inserting "(b)" before "Subject matter"; and

(3) by adding at the end thereof the following new subsections:

"(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if—

"(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section;

"(2) the claimed process is a biotechnological process as defined in subsection (d); and

"(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

"(B) claims to the process and to the machine, manufacture, or composition of matter—

"(i) are entitled to the same effective filing date; and

"(ii) appear in the same patent application, different patent applications, or patent which is owned by the same

person and which expires or is set to expire on the same date.

"(d) For purposes of this section, the term 'biotechnological process' means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material.".

SEC. 102. NO PRESUMPTION OF INVALIDITY.

The first unnumbered paragraph of section 282 of title 35, United States Code, is amended by inserting after the second sentence "A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.".

SEC. 103. EFFECTIVE DATE.

The amendments made by this title shall apply to all United States patents granted on or after the date of the enactment of this Act and to all applications for United States patents pending on or filed after such date of enactment, including any application for the reissuance of a patent.

TITLE II—BIOTECHNOLOGICAL MATERIAL PATENTS

SEC. 201. INFRINGEMENT BY IMPORTATION, SALE OR USE.

(a) INFRINGEMENT.—Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"(h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by using a biotechnological material (as defined under section 154(b)) which is patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the term of such patent.".

(b) CONTENTS AND TERM PATENT.—Section 154 of title 35, United States Code, is amended—

(1) by inserting "(a)" before "Every";

(2) by striking out "in this title," and inserting in lieu thereof "in this title (1)";

(3) by striking out "and, if the invention" and inserting "(2) if the invention";

(4) by inserting after "products made by that process," the following: "and (3) if the invention is a biotechnological material used in making a product, of the right to exclude others from using or selling throughout the United States, or importing into the United States the product made or using such biotechnological material,"; and

(5) by adding at the end thereof the following:

"(b) For purposes of this section, the term 'biotechnological material' is defined as any material (including a host cell, DNA se-

quence, or vector) that is used in a biotechnological process as defined under section 103(d).".

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by this section shall take effect six months after the date of enactment of this Act and, subject to paragraph (2), shall apply only with respect to products made or imported after the effective date of the amendments made by this section.

(2) EXCEPTIONS.—The amendments made by this section shall not abridge or affect the right of any person, or any successor to the business of such person—

(A) to continue to use, sell, or import products in substantial and continuous sale or use by such person in the United States on the date of enactment of this Act; or

(B) to continue to use, sell, or import products for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investment made or business commenced in the United States before such date.

VI. SECTION-BY-SECTION ANALYSIS

TITLE I. BIOTECHNOLOGICAL PROCESS PATENTS

Section 101. Conditions for patentability; Nonobvious subject matter

Section 101 would amend section 103 of title 35, United States Code, to ensure that under certain circumstances, a biotechnological process would not be considered obvious if it either makes or uses a machine, manufacture, or composition of matter that itself is novel and nonobvious. To obtain this determination, the product and process claims must be sought to be patented in the same application. Continuing applications would also be eligible where the specified conditions are met.

The amendment to section 103 would thus provide a mechanism for applicants to avoid a conclusion that a biotechnological process of making or using a patentable product is obvious under this section, overruling the decision in *In re Durden,* 763 F.2d 1406 (Fed Cir. 1985). Process patents granted under 103(c) would not affect an existing process patent right.

With regard to patent terms, section 101 provides that process claims that are granted the benefits of the nonobviousness rule under subsection 103(c) must coterminate with the product claims on which they depend for patentability. The purpose of this provision is to prevent a patent applicant from obtaining an effective patent term in excess of seventeen years (and any applicable patent term extension) on what would be essentially a single invention.

The committee does not intend to deprive independently patentable inventions of the patent terms to which they are entitled under current law. Therefore, if an applicant elects to demonstrate the independent patentability of a process, notwithstanding a possible *Durden* rejection, rather than rely on the nonobviousness rule established in the legislation, the invention is entitled to the full 17-year term (and any applicable patent term extension) available

under current law for both product and process inventions, without cotermination.

Thus, applicants have the option of either demonstrating the independent patentability of a process (as must be done under current law) or proceeding under the nonobviousness rule established by this legislation. Independent patentability may be demonstrated, for example, by showing the nonobviousness of the process (for example, through proof that the process demonstrates unpredictable results).

Applicants who unsuccessfully attempt to demonstrate independent patentability do not forfeit their right to amend their application to one that relies upon the rule established by this legislation. However, an applicant who so amends his application is required to have his process claims coterminate with his product claims. In such cases, patent term extension will continue to be available to extend the term beyond the termination date otherwise established.

Section 101 would simplify and provide certainty in the determination of patentability of biotechnological processes using or making novel and nonobvious products, for applicants who comply with its requirements.

This legislation would also make our patent law consistent with the patent granting process now practiced in the European and Japanese Patent Offices. Under the law of these trading partners, process claims are granted automatically.

Section 102. Presumption of validity

Since an application may rely on the nonobviousness rule established in this legislation to expedite issuance of his or her process claims rather than risk the costs and delays involved in overcoming a *Durden* rejection, section 102 provides that there is no presumption that process claims are invalid if the product claims, which form the basis for invoking the nonobviousness rule, are invalidated. This does not mean that such process claims will be treated as not obvious; rather the inventor must show that such a process is not obvious without relying on this legislation. Any litigation should provide the patentee with the opportunity to prove that the process claims are independently patentable.

Section 103. Effective date

The amendments made by this act are effective on the date of enactment. The amendments apply to all patents granted on or after the date of enactment, all patent applications pending on the date of enactment, and all patent applications filed after the date of enactment. Patent applications include applications for reissuance of a patent.

TITLE II. BIOTECHNOLOGICAL MATERIAL PATENTS

Section 201. Infringement by importation, sale or use

Section 201 would close the loophole that currently allows foreign exploitation of patented biotechnological material (through the unfair use of such materials offshore tomake a commercial product) by amending section 271 of title 35, United States Code, to provide

that it is an act of infringement for any person who wrongfully imports into the United States or sells or uses within the United States a product made by using a patented biotechnological material. Under the bill's definition, a biotechnological material is any material that is used in a biotechnological process. This includes, but is not limited to, host cells, DNA sequences, and vectors.

Under this section, a person may continue to use, sell, or import products so made if the products are being used or sold in a substantial and continuous manner on the date of enactment. A person may also continue to use, sell, or import products if substantial preparation to do so was made before the date of enactment, keeping in mind the value of the invention and the need to protect innovation from free riding.

Section 201 would take effect 6 months after the date of enactment and shall only apply to products made or imported after the effective date of the amendments made by this section.

VII. Cost Estimate

In accordance with paragraph 11(a), rule XXVI, of the Standing Rules of the Senate, the committee offers the report of the Congressional Budget Office:

U.S. Congress,
Congressional Budget Office,
Washington, DC, May 10, 1993.

Hon. Joseph R. Biden, Jr.,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has reviewed S. 298, a bill to amend title 35, United States Code, with respect to patents on certain processes, as ordered reported by the Senate Committee on the Judiciary on April 8, 1993. CBO estimates that enactment of S. 298 would result in no significant costs to the federal government and in no costs to state and local governments. Enactment of S. 298 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to the bill.

Title I of S. 298 would expand the definition of non-obvious subject matter for purposes of patentability. The title also would prohibit the Patent and Trademark Office from holding invalid a patent claim for a process solely because the end product or the items used in the process lack novelty or are obvious.

Title II would make liable for patent infringement those who import, sell, or use patented biotechnological material without the patent holder's authorization.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is John Webb.

Sincerely,

Robert D. Reischauer,
Director.

VIII. Regulatory Impact Statement

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has concluded that no significant additional regulatory impact would be incurred in carrying out the provisions of this legislation. After due consideration, the committee concluded that the changes in existing law contained in the bill will not increase or diminish any present regulatory responsibilities of the U.S. Department of Commerce or any other department or agency affected by the legislation.

IX. Changes in Existing Law

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 298, as reported, are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

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TITLE 35—PATENTS

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CHAPTER 10—PATENTABILITY OF INVENTIONS

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§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained through though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(b) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. (Added November 8, 1984, Public Law 98–622, sec. 103, 98 Stat. 3384.)

(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if—

(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section;

(2) the claimed process is a biotechnological process as defined in subsection (d); and

(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignments to the same person; and

(B) claims to the process and to the machine, manufacture, or composition of matter—

(i) are entitled to the same effective filing date; and

(ii) appear in the same patent application, different patent applications, or patent which is owned by the same person and which expires or is set to expire on the same date.

(d) For purposes of this section, the term "biotechnological process" means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material.

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CHAPTER 14—ISSUE OF PATENT

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§ 154. Contents and term of patent

(a) Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, *for the term of seventeen years,* subject to the payment of fees as provided for [in this title] *in this title, (1)* of the right to exclude others from making, using, or selling the invention throughout the United States [and, if the invention], *(2) if the invention* is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process, *and (3) if the invention is a biotechnological material used in making a product, of the right to exclude others from using or selling throughout the United States, or importing into the United States the product made or using such biotechnological material,* referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof. (Amended July 24, 1965, Public Law 89–83, sec. 5, 79 Stat. 261; December 12, 1980, Public Law 96–517, sec. 4, 94 Stat. 3018; August 23, 1988, Public Law 100–418, sec. 9002, 102 Stat. 1563.)

(b) For purposes of this section, the term "biotechnological material" is defined as any material (including a host cell, DNA sequence, or vector) that is used in a biotechnological process as defined under section 103(d).

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CHAPTER 28—INFRINGEMENT OF PATENTS

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§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

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(h) Whoever without authority imports into the United States or sells or uses within the United States a product which is made by using a biotechnological material (as defined under section 154(b)) which is patented in the United States shall be liable as an infringer if the importation, sale, or use of the product occurs during the term of such patent.

CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

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§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. *A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition of matter is determined to lack novelty under section 102 of this title or to be obvious under section 103 of this title.* The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

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